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Abstract:

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(71) Applicant: McNeilab, Inc.
Springhouse Pennsylvania 19477(US)

(72) Inventor: Troutner, Vernon H.
6221 58th Avenue North
St. Petersburg, FL 33709,(US)

(74) Representative: Jones, Alan John et al
CARPMAELS & RANSFORD 43 Bloomsbury Square
London, WC1A 2RA(GB)

(54) **Demountable peristaltic pump for photoactivation patient treatment system.**

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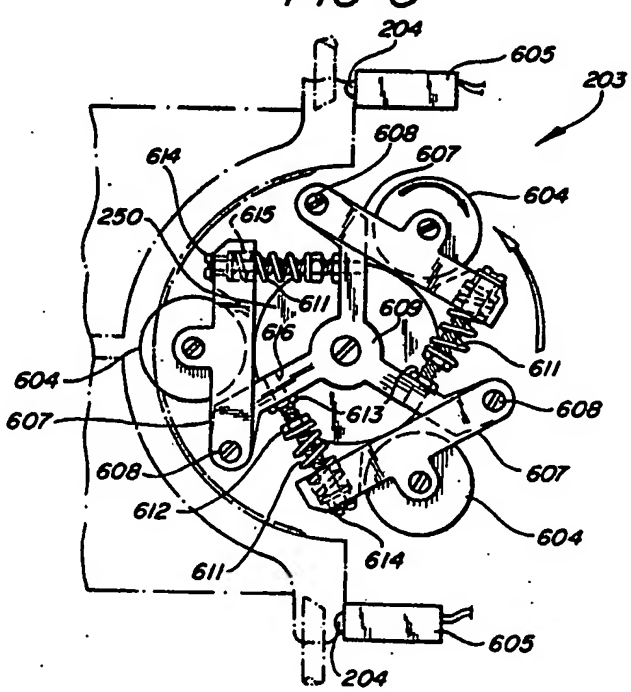
FIG-6



EP 0 239 255 A1

DEMOUNTABLE PERISTALTIC PUMP FOR PHOTOACTIVATION PATIENT TREATMENT SYSTEM

This invention relates to the field of treating cells with photoactivatable compounds and radiation which activates the compound thereby affecting the cells and specifically, relates to clinically useful systems for the extracorporeal treatment of blood cells, and more particularly to radiation chamber pump blocks and a demountable peristaltic pump therefor.

It is well-known that a number of human disease states may be characterized by the overproduction of certain types of leukocytes, including lymphocytes, in comparison to other populations of cells which normally comprise whole blood. Excessive or abnormal lymphocyte populations result in numerous adverse effects to patients including the functional impairment of bodily organs, leukocyte mediated autoimmune diseases and leukemia related disorders many of which often ultimately result in fatality.

U.S. Patent Nos. 4,321,919; 4,398,906; 4,428,744; and 4,464,166 to Edelson describe methods for treating blood whereby the operation or viability of certain cellular populations may be moderated thereby providing relief for these patients. In general, the methods comprise treating the blood with a dissolved photoactivatable drug, such as psoralen, which is capable of forming photoadducts with DNA in the presence of U.V. radiation. It is believed that covalent bonding results between the psoralen and the lymphocyte nucleic acid thereby effecting metabolic inhibition of the thusly treated cells. Following extracorporeal radiation, the cells are returned to the patient where they are thought to be cleared by natural processes but at an accelerated pace believed attributable to disruption of membrane integrity, alteration of DNA within the cell, or the like conditions often associated with substantial loss of cellular effectiveness or viability.

Although a number of photoactivatable compounds in the psoralen class are known, 8-methoxy psoralen is presently the compound of choice. An effective radiation for this compound, and many psoralens in general, is the ultraviolet spectrum in the range of approximately 320 to 400 nanometers, alternatively referred to as the U.V.A. spectrum. As the development of photoactivatable compounds proceeds, it may be expected that changes in the preferred activation radiation spectrum will be necessary. Suitable selection of radiation sources will, of course, increase treatment efficiency and is contemplated as an obvious optimization procedure for use with the inventions disclosed herein.

Although Edelson's methods have been experimentally shown to provide great relief to patients suffering from leukocyte mediated diseases, numerous practical problems require solutions. In particular, Edelson fails to provide a suitable apparatus for applying radiation to the cells, e.g. via a treatment station, in an economical and efficacious manner, or a system for incorporating a treatment station providing for the treatment of a patient in a clinically acceptable format.

Conventional techniques for photoactivating compounds associated with cells have relied on a plurality of devices including flasks, filtration columns, spectrophotometer cuvettes, and petri dishes. The sample to be irradiated is added to the containers and the container placed adjacent to the radiation source. Such systems tend to be laboratory curiosities as they fail to provide the necessary safeguards intrinsically necessary where patient bodily fluids are concerned, particularly since these fluids must be returned to the patient thereby necessitating strict avoidance of contamination. Further, such methods tend to be volume limited, are characterized by many mechanical manipulations and are generally unacceptable from a clinical and regulatory viewpoint. It is an object of the present invention to provide methods and apparatus suitable for use with the Edelson methods to overcome the limitations associated with the conventional expedients.

EP-A-O 138 489 describes a practical device for coupling the radiation provided by commercially available light sources, such as the so-called "black-light" fluorescent tubes, to cells for treatment by Edelson's photoactivated drug methods. In summary, the disposable cassette described therein comprises a plurality of fluorescent tube-like light sources such as the U.V.A. emitting Sylvania F8TS/BLB bulb, which are individually, coaxially mounted in tubes of larger diameter which are, in turn, coaxially mounted in sealing arrangement within second outer tubes of even larger diameter thereby forming a structure having two generally elongated, cylindrical cavities about each radiation source. The inner cavity preferably communicates with the atmosphere thereby facilitating cooling of the radiation source. The second tube forming the outer cavity further comprises inlet and outlet means for receiving and discharging, respectively, the cells to be irradiated. A plurality of these structures are "ganged" and suitable connections made between inlets and outlets of adjacent members to provide for serpentine flow of cells through each outer cavity. Thus, continuous flow of the cells through the plurality of cavities surrounding the centrally disposed radiation sources facilitates thorough treatment of the cells. Additional, detailed description of the above device may be obtained by direct reference to EP-A-O 138 489.

To be fully practical, the device requires a clinically acceptable instrument to house the device and to provide the cells to be treated in an appropriate form. Such an instrument is the object of the inventions described in U.S. Patent Nos. 4,573,960, 4,568,328, 4,578,056, 4,573,961, 4,596,547, 4,623,328, and 4,573,962.

While the instruments described therein work well, it is an object of the instant application to describe improved systems capable of implementing, in advanced fashion, the medical treatment principles first taught by Edelson.

It is another object of the present invention to provide still further improvements in greater patient safety and comfort while reducing treatment time and cost, by utilizing a newly designed disposable irradiation chamber in an appropriate instrument which incorporates a U.V.A. light array assembly and a peristaltic pump to operate in conjunction therewith.

It is yet another object to provide an improved instrument which meets the above criteria while maintaining the positive attributes of the prior system; compactness, mobility, completeness, fully automated and monitored, coupled with ease of operation.

It is a further related object of this invention to provide, in contrast to the time consuming batch like processing of the prior system, continuous on-line patient treatment wherein collection, separation, and cell treatment occur simultaneously, thereby reducing treatment time and increasing patient safety and comfort.

These and still other objects of the invention will become apparent upon study of the accompanying drawings wherein:

Figure 1 illustrates a preferred configuration of the system during collection, separation, and treatment;

Figure 2 shows a side view of the irradiation chamber, recirculation pump, and light source array;

Figure 3 shows a bottom view of the apparatus in Figure 2;

Figure 4 shows a side view of the arcuate portion of the pump block with tubing installed;

Figure 5 shows the unmounted pump block without irradiation chamber, tubing, or other attachments; and

Figure 6 shows the demountable peristaltic pump.

In accordance with the principles and objects of the present invention there is provided a demountable peristaltic pump for use in combination with a pump block associated with an irradiation chamber used in a patient treatment system for "on-line" extracorporeally photoactivating a photoactivatable agent in contact with blood cells by collecting and separating on a continuous basis, blood from a patient while the patient is connected to the system, returning undesired blood portions obtained during separation while the desired portion is photoactivatably treated and thereafter returning the thusly treated cells to the patient. As a result of this novel approach, the treatment system of the instant inventions optimizes and minimizes treatment time by concurrently conducting various aspects of such photoactivation treatment which were previously performed sequentially. More specifically, the apparatus collects and separates blood on a continuous basis as it is withdrawn from the patient and returns unwanted portions to the patient while concurrently energizing the irradiation sources for photoactivating the photoactivatable agent in contact with the desired blood portion. Following photoactivation, the treated cells may then be facilely returned to the patient utilizing a drip chamber gravity feed infusion line incorporated in the tubing set. The preferred embodiment of the instant invention provides for a novel peristaltic pump - pump block - irradiation chamber combination which yields surprising efficiency in terms of ease of use, safety, and elimination and simplification of previously required components.

Figure 1 shows various aspects of the system developed for extracorporeally treating a patient based in part upon the scientific discoveries of Edelson. The specific design, construction and operation of the apparatus 10 is the result of a number of separate inventions some of which form the subject matter of previously described issued US patents and published European patent applications.

Some form the subject matter of the following concurrently filed European patent applications:

Application Number	Publication Number	US Priority Application Number	Applicants Reference
		834 292	JJC 2
		834 293	JJC 3
		834 294	JJC 4
		834 303	JJC 5
		834 256	JJC 6
		834 257	JJC 7
		834 259	JJC 9
		834 258	JJC 14

A brief description of the contents of these applications is included herein.

The operation of the device and performance of the methods can be divided into two basic phases or modes, depicted in part by Figure 1. The first phase is shown substantially in Figure 1 wherein the patient is connected at the point shown, preferably by venipuncture or the like methods well-known and developed to a high degree in the dialysis arts. Patient blood, as it flows to the apparatus 10 (alternately referred to herein as the puvapheresis apparatus or system) is preferably infused, under control of pump 11, with an anticoagulant agent contained in container 20 hung from stand 15. Control of the flow of patient blood to the remainder of apparatus 10 is controlled largely by clamping means 16a which has the dual function of also controlling flow in the reverse direction as well as flow to return container 21. Clamp 16a acts as an "or" valve.

Normally the blood flows through tubing 24 through blood pump 12 (preferably a roller pump such as that described in U.S. Patent No. 4,487,558 to Troutner entitled "Improved Peristaltic Pump" and incorporated herein by reference) into continuous centrifuge 13. This continuous centrifuge, available commercially from suppliers such as Dideco, Haemonetics, and others, is preferably capable of continuously separating blood based on the differing densities of the individual blood components. "Continuously", as used herein means that, as blood flows into the centrifuge through line 24, it accumulates within the rotating centrifuge bowl and is separated so that low density components are emitted after a certain minimum volume has been reached within the centrifuge bowl and as additional blood is added. Thus, the continuous centrifuge in effect acts as a hybrid between a pure online system and a pure batch system. This occurs because the centrifuge bowl has a capacity to hold most, if not all, of the most dense portion, typically erythrocytes or red blood cells while emitting lower density portions such as plasma and leukocytes (white blood cells) as whole blood is continuously added. At some point, however, the reservoir volume of the centrifuge is filled with the higher density components and further separation cannot be effectively obtained. Prior to that point, the operator, by viewing the uppermost portion of the centrifuge bowl through the centrifuge cover, can detect qualitatively when the centrifuge emits plasma (as opposed to priming solution), leukocyte enriched portions and the remainder, i.e., nonleukocyte enriched portions, including erythrocyte enriched portions. Based on the operator's observations, he or she enters through control panel 19 (specifically via panel portion 42) the identification of the individual blood portions as they are emitted from the centrifuge. This information is entered by keys 44 (e.g. PLASMA, BUFFY COAT or leukocyte enriched portion) on control panel 19, (shown in Figure 1) and in response thereto, the apparatus 10 controls valve mechanism 16c to direct the leukocyte enriched portion and a predetermined volume of plasma into plasma-leukocyte enriched container 22 while excess plasma, air, priming fluids, erythrocytes etc. are directed to container 21.

Once the centrifuge is no longer capable of further separation due to the attainment of its capacity, the operator directs that the bowl be emptied by suitable data key entry on panel 19 and the fluid contents of centrifuge 13 are advantageously pumped into return container 21 by means of pump 12 under the control of valves 16a and c. The foregoing steps may be repeated a number of times or cycles before the desired volume of leukocyte enriched blood and plasma is obtained for further treatment, in each instance the undesired portions being collected in return container 21.

Between cycles, the fluids, including erythrocytes which have been pumped into return bag 21 are gravity fed back to the patient through a drip infusion operation and controlled by valve 16b. It is preferred that gravity feed be employed rather than pumping the blood back to the patient via pump 12 in order to avoid potential pressurization problems at the infusion insertion site at the patient, and also to avoid foaming or other air related dangers.

As may be already appreciated, when initially set up, the centrifuge bowl and line 24 may be expected to contain sterilized air which is preferably removed by suitable priming operations advantageously accomplished by utilizing the anticoagulation agent in container 20; both the air and a portion of priming solution being collected in container 21.

Also to be noted is the predetermination of the desired leukocyte enriched volumes and plasma volume to be collected within container 22 as well as the number of cycles to be employed to collect same. These volumes are selected largely in accordance with the individual volume capacities of the containers as well as the treatment chamber to be described later. Accordingly, these volumes are set in order to preferably optimize handling efficiency and to ensure patient safety. For instance, one preferred selection would include the following settings: 250 ml total buffy coat or leukocyte enriched portion and 300 ml of plasma to be collected within container 22. This might require any number of cycles, preferably on the order of three or four, bearing in mind that the more cycles that are selected, the lower the total volume of blood withdrawn from the patient at any one time. If blood collection meets the minimum capacity limits of the centrifuge bowl, the patient's capacity to withstand temporary blood volume depletions and the treatment procedure in general is increased. Further, more cycles will permit more discriminating selection of leukocyte enriched blood as it is emitted from the centrifuge. The buffy coat and plasma volumes as well as the number of cycles are typically physician selected. Accordingly, the controls governing these selections are preferably placed within the apparatus 10, such as behind door 18a where their inadvertent alteration may be advantageously avoided, especially since no operator interaction is normally required with respect to these data inputs.

The leukocyte enriched container 22 is connected via tubing line 34 to the flat plate treatment chamber behind assembly door 17 with a return line 35 to reservoir container 22.

Referring now to Figures 2 and 3, the leukocyte enriched blood, plasma, and priming solution contained in reservoir 22 (Figure 1) is delivered through line 34 to the inlet 209 of the flat plate irradiator 200. The cavity in the flat plate is relatively "thin" (e.g. on the order of approximately 0.04 inch) in order to present large surface area of leukocyte rich blood to irradiation and reduce self-shielding effects encountered with lower surface area/volume ratios. The fluid flows upward through the serpentine pathway in cavity 208 in the irradiator chamber to the outlet 210. Tubing from the outlet 211 passes through the pump block 201 [described in greater detail in EP-A (JJC-7)], affixed to the end of the flat plate irradiator 200, and then connects to return line 35 which returns fluids from the irradiation chamber to container 22.

Recirculation pump rotor 203, which is located internally in the machine (mounting not shown), engages the tubing in the pump block in the semi-circular tract 212 and thereby provides and controls the recirculating flow of fluid, from container 22 up through irradiation chamber 200 and back to container 22. In a preferred embodiment, a metal segment 220 in the tubing line from outlet 211 incorporates a thermocouple 213 [described more fully in EP-A- (JJC-4)] which permits monitoring of the fluid temperature.

Sterile air initially contained in the irradiation chamber cavity 208 is displaced by entering fluid and stored in the top of container 22. By reversing the rotation of recirculation pump rotor 203, the air stored in container 22 can be pumped back into the outlet 210 of the chamber 200 thereby displacing all fluids back into container 22. Once fluid is initially delivered to container 22, the recirculation pump rotor 203 is energized filling the irradiation cavity 208 and displacing sterile air to container 22. When the irradiation chamber is filled and BUFFY COAT button 44 on panel 19 is pressed, the light array assembly which surrounds the irradiation chamber is energized. Continued operation of the recirculation pump rotor 203 continuously recirculates the leukocyte enriched fluid from container 22 through the chamber for receiving photoactivating radiation from the energized light array assembly 401 (Figure 3) and back to container 22.

Figure 3, illustrating the light array assembly 401 from a bottom view, shows two rows, in the most preferred embodiment although one row can be used, of radiation source 400 powered through contacts 216. Such sources are conveniently chosen so that illumination is reasonably constant over the entire irradiation cavity 208 (Figure 2). Suitable sources include the Sylvania FR15"T8/350BL/HO/180° with 2011 phosphorus bulb which is in the so-called fluorescent tube form. As is apparent from Figure 3, the irradiation chamber 200 slides between the rows of radiation source 400 so that pump block 201 engages pump rotor 203 driven by motor 250. Other aspects of the radiation array 400 are discussed in EP-A- (JJC-6).

Thus, photoactivation of the leukocyte enriched fluid by irradiation is initiated at the outset and continues through and after the collection and separation process. In the most preferred mode, the light array assembly [described more fully in EP-A- (JJC-6)] will comprise sources of ultraviolet radiation, most preferably of the UVA type for activating the photoactivatable agent presently of choice, 8-methoxy psoralen.

The flat plate irradiation chamber treatment module is described more fully in EP-A- (JCC-14)

In operation, and with respect to Figure 1, the exposure time via knob on the right hand portion of the panel 43 is set in accordance with physician determined criteria. The central control processor of the apparatus 10, calculates and displays via central processing unit and memory stored software, the exposure time remaining at the onset of irradiation treatment and as the treatment progresses. The right section of the control panel also includes three operator controlled entry data keys 44 whereby the operator can de-energize the photoactivating light array and stop the recirculation process if desired. Actual photoirradiation treatment preferably commences automatically under control of the central processing unit when fluid is first directed to container 22, continues while leukocyte enriched blood portion from container 22 is pumped through the irradiation chamber back into container 22, and terminates when the preset exposure time has expired. At that time, the light array assembly is de-energized and the recirculation pump reverses emptying the contents of the irradiation chamber 200 (Figure 2) into container 22.

Thereafter container 22 is ideally removed to stand 15 (Figure 1) where it is connected to tube 38, provided on the common drip chamber 21a also associated with return container 21, for reinfusion of the treated blood portion into the patient.

To enhance patient safety and decrease the risk of contamination to the patient blood and blood portions, each time a connection is made or broken, it is preferably only done once. Thus, container 22 would ideally have four connection points or ports; one for the collection of the leukocyte enriched blood portion, two for connection to the flat plate irradiation chamber (feed and return), and the fourth for connection to the drip chamber (21a) for reinfusion of treated blood to the patient.

With further reference to Figure 1, the control panel 19 of the apparatus 10 is shown with the keyboard entry buttons 44, each ideally having a light which, when lit, preferably indicates the stage of the operation. As will be noted, the keyboard entry buttons 44 are preferably placed in sequential order thereby assisting the operator in learning the system and performing the steps in the correct order. Indeed, the central control microprocessor will preferably be programmed to prevent out of step sequences from being implemented. A visual display indicates the volume of leukocyte enriched blood collected in container 22.

Panel 19 will preferably also contain a power switch, as well as a blood pump speed control whereby the operator may select the speed with which the blood is withdrawn from the patient and pumped through the system during collection. Also preferably included is an alpha-numeric display for indicating the machine's status and identifying alarm conditions throughout system operation. Optional accessory status lights, preferably provided in green, yellow, and red colors, provide at a glance the overall operating status of apparatus 10. Further included is a mute/reset button for quieting an audible alarm activated in the event an alarm condition occurs and operator input is required.

Other features may be readily apparent from the drawings such as the preferable inclusion of casters and caster brakes for enhancing the mobility of the apparatus. Further, side panel 23 will preferably include mechanical means (e.g. hanging pegs and the like) for assisting in the securement of container 22. It may also optionally be outfitted with a transparent or translucent opening 18b in the area beneath container 22 for providing at a glance information regarding the illumination status of the irradiation treatment chamber during the treatment phase. For instance, if the window is of sufficient size, the operator may readily determine that each irradiation source within the treatment chamber is illuminated as desired. Naturally, the material comprising such window is preferably selected in order to contain harmful radiation, if any, within apparatus 10.

The aforedescribed photopheresis blood treatment apparatus is made largely possible by an automated control method for directing the blood portions, derived from the continuous centrifuge, into particular containers. The automated method performs in accordance with preset volume determinations which are manually entered behind panel 18a pursuant to a physician's direction. These predetermined volumes specify the volume to be contained within container 22 by setting forth the volume of plasma and the volume of leukocyte enriched blood portion to be directed thereto. Additionally included within these condition setting parameters is preferably the ability to set forth the number of cycles of blood collection and separation required or desired in order to obtain the desired blood volumes.

The volumes collected are determined in accordance with the blood volume pumped by the blood pump. This may be suitably monitored and communicated to the central control means by specifically monitoring the number of step pulses input to the pump to cause rotation of the blood pump. Typically, 200 pulses results in one revolution. Rotation may also be conveniently monitored such as by attachment of a slotted disk to the shaft and the passage of slots determined by an optical sensor means such as that described in US-A-4 623 328 and by monitoring shaft rotation. The resultant periodic signal may be conveniently correlated with speed and number of rotations by circuit designs well-known in the art. The number of rotations by any of the foregoing methods coupled with the known volume pumping characteristics of the pump , will provide the necessary information regarding the volume of blood pumped. It will readily be appreciated that the sensors need not be optical but may be electronic or mechanical instead.

In actual operation, a most preferred procedure would be as follows. The operator presses the PRIME CENT. key on control panel section 19 which primes the tubing set, the blood pump, and the centrifuge with the anticoagulation solution contained in container 20. Displaced sterile air is collected in container 21. When priming solution emerges from the exit of the centrifuge, the operator presses PRIME UV key on control panel section 42 which closes the tubing line to container 21 and opens the tubing line to container 22 by means of valve 16c. Recirculation roller pump rotor 203 is energized to prime the flat plate irradiation chamber and displace sterile air to container 22. The priming process stops automatically after a preset volume of fluid is delivered to container 22.

Blood collection is started by the operator pressing START key on control panel. Thereafter, blood is withdrawn from the patient and pumped by the blood pump into the rotating centrifuge. As the blood enters the centrifuge, it displaces the priming solution which emerges first in accordance with its preferably lighter density. This priming solution is automatically directed into container 22 until a preset volume is delivered, after which the emerging solution is redirected to container 21 by means of valve 16c. At some point, the priming solution will be completely displaced from the rotating centrifuge and plasma will begin to emerge. This emergence may be directly observed through port 14 whereupon the operator presses the PLASMA key on control panel 19. Thereafter, the central control means automatically directs the plasma into container 22 by altering valve 16c keeping track of the volume as it does so since the volume entering the centrifuge equals the volume emerging therefrom. This continues until the operator indicates the leukocyte enriched portion, i.e. buffy coat has begun by pressing the respective data entry key in control panel section 42 whereupon, the leukocyte enriched portion continues to container 22, however, the volume so directed is monitored as buffy coat volume. Alternately, if all of the predetermined plasma volume is collected prior to the emergence of the buffy coat, then the central control means automatically diverts, by valve 16c, the emerging plasma fluid stream to container 21. In that instance, upon the emergence of the buffy coat and the keying of the BUFFY COAT data entry switch 44, the central control means diverts the emerging buffy coat into container 22, by means of valve 16c, again keeping track of its volume.

The collection of the buffy coat will preferably continue in accordance with both the predetermined buffy coat volume as well as the number of cycles, another condition predetermined by the physician. If this most preferred embodiment is employed, then a representative example might be as follows. Assume, that the predetermined volume and cycle conditions are set as follows: 350 mls of plasma, 250 mls of buffy coat, and 5 cycles. In each cycle, the apparatus will collect 250/5 or 50 mls of buffy coat before ending the cycle and thereupon emptying the centrifuge bowl and returning all nonleukocyte fluids, predominantly erythrocytes and perhaps excess plasma, to the patient. Prior to the collection of the 50 mls, plasma will emerge from the centrifuge and will be collected in container 22 either until the full 350 mls are collected or, until the buffy coat emerges.

During the next cycle, the central control microprocessor or computer will direct the further collection of plasma, if needed, in order to reach the 350 ml predetermined volume and then collect an additional 50 mls of buffy coat. The total volume to be contained within container 22, will then equal 600 mls and would be indicated on display 46 as it is accumulated.

Thus, the instant invention serves to automatically keep track of the volumes as they are collected thereby facilitating the institution of a convenient number of cycles whereby the removal of large blood volumes from the patient is avoided. Not only is patient safety enhanced thereby, but the automated nature of the procedure further increases safety since, in accordance with the programmed conditions supplied to the central control microprocessor, the operator need not attempt to keep track of plasma and leukocyte enriched volumes collected, while still being assured that the final solution for treatment will contain the predetermined and desirable leukocyte concentration.

The foregoing described automated methods used in the photopheresis apparatus described with respect to Figures 1, 2, and 3 depend heavily upon the instant invention, in particular a demountable peristalitc roller pump within the apparatus which automatically interfaces with a pump block associated with the flat plate irradiation chamber.

With specific reference to Figures 4, 5 and 6, the pump block 201 is affixed to the end of flat plate irradiator 200 after assembly of the molded female and male halves forming the serpentine pathway 208. To install the irradiation chamber into the patient treatment apparatus, door 17 is opened and the irradiation chamber 200 inserted so that the pump block enters first. In its fully installed position the chamber is positioned with fluid cavity 208 centrally located within the irradiation field of the light array assembly and the pump block engages electronic and mechanical elements affixed within the patient treatment apparatus 202.

Connected to outlet port 210 is flexible tubing 211 contained within track-like recesses 224 which retain the tubing in the pump block 201 and around pump race 212. The tubing is further contained with a similar recess within chamber 200 and exits as outlet 35. A preferred embodiment will incorporate a stainless steel tubing segment 220 inserted into tubing 211. Attached to the stainless steel tubing is a thermally connected thermocouple 213 described more fully in EP-A- (JJC-4) having leads for electrical connection to the treatment apparatus. As the block moves into its fully engaged position, the thermocouple leads retained in features 225 engage thermocouple contacts 221 providing a temperature indicating signal to the temperature monitoring circuitry 205 contained within the apparatus (not shown). Tubing 211 follows an arcuate wall of approximately 130 degrees in the arcuate track 212 which engages recirculation pump rotor 203. The center of rotation of rotor 203 is at the radial center of arcuate track 212. Spring biased rollers on the rotor engage tubing 211 within track 212 causing fluid to be pumped through the tubing 211. Shoulder means such as expanded tubing sections 219 are affixed to tubing 211 at both ends of track 212 and retained in pump block cavities 226 to prevent creeping movement of the tubing within the arcuate track during pumping action.

As the block moves into its engaged position, ideally two pins 204 enter mating pump cavities in the face of the pump block thereby ensuring alignment of mating the pump block with the pump rotor.

Slots 229 are provided for engagement with mechanical levers which urge the pump block into position with the pump rotor. Ideally, the tubing within the pump arc is automatically positioned when the chamber-pump block assembly is slid into position such that the tubing is brought into contact with at least one of the rollers 604 to effect compression of the tubing at the point of contact. This eliminates the prior and conventional need to thread the tubing through the pump. The instant invention also eliminates the long and complex tubing that would otherwise be required if the pump were mounted externally on the apparatus thereby reducing both complexity and cost of the tubing set, and greatly simplifying its use.

With specific reference to Figures 4 and 6, the peristaltic roller pump engagable pump block 600 comprises an arcuate track 212 having an angle ϕ greater than 360°/# of rollers in the peristaltic pump or 120° in the case of a 3 roller pump, and equal to or less than 180°, preferably 130° to 160° and most preferably about 150° for a 3 roller pump. The angle ϕ is formed by the intersection of radial lines drawn from the center of the arcuate track to the ends of the arcuate track, bounded by lead-in tracks 601 and 602 into which is placed the flexible tubing pump segment 603.

In use, the pump block 600 containing the pump tubing segment is ideally positioned such that the center of arcuate track 212 ideally coincides with the center of rotation of pump rotor assembly 203 and is positioned such that the rollers 604 of the rotor can enter track 212 and compress and occlude tubing segment 603. One or more positioning blocks 605 with alignment features 606 adapted to mate with receiving receptacles in block 600 can be advantageously used to accurately position the block with respect to the rotor. Obvious alternative mechanical means to accomplish substantially the same purposes will readily occur to those skilled in the art.

In the most preferred embodiment, three rollers 604 spaced 120° apart are axially mounted on swing arms 607 which are pivotally mounted 608 to radial arms of the central hub 609. The hub in turn is connected to electric motor 610 which rotates the pump rotor assembly. At the end of each swing arm 607 opposite pivot 608 is a bored hole 615 through which a machine screw 614 freely passes and is threaded into the radial arm of the hub at 616. Adjustment of screw 614 advantageously sets the maximum outward movement (from the center of pump 203) of the rollers 604. Nut 613 locks this adjustment. A compression spring 611 surrounds the screw 614 with one end bearing against the underside of the swing arm 607 and the other end bearing against adjusting nut 612 which is threaded onto screw 614. Resilient spring 611 biases the rollers in an outward direction with a force adjustable by the nut 612. In practice, the spring

tension is set to a sufficient force to compress and acclude tubing 603. Since the roller spacing is 120° and the arcuate track 212 is greater than 120°, at least one roller is always compressing tubing 603 and rotation of the roller rotor assembly in either direction will cause a pumping action for fluids or gas contained within tubing 603.

Thus, the instant invention provides for the demounting or separation block 600 having an arcuate track and fluid pumping tubing mounted therein from a peristaltic rotor assembly permanently associated with the patient treatment apparatus for facilitating the insertion of the disposable irradiation chamber associated with the pump block. This unexpected advantage is attributable in part to the use of three or more rollers instead of the more usual two which permits the use of a pumping track of less than 180° thereby resulting in a more open arcuate track facilitating engagement of the rollers in a shallower or smaller block. Such an open arc is more easily, securely, and predictably mated with the rotor assembly thus improving ease of use and patient safety. Further, unlike the case with peristaltic pumps having only two rollers, engagement of the arcuate track with the roller pump in the instant invention, does not require compression of the rollers due to the greater patentcy of the arcuate track. Location of the rollers between the pivot point and the adjusting spring permits a lighter spring to exert greater roller force to facilitate occlusion particularly since the force is essentially constant for small radial movement of the roller.

Upon study of the accompanying figures, and the foregoing description, it will become readily apparent to the skilled artisan that numerous mechanical alterations may be made to the foregoing without departing from either the spirit or scope of the instant invention.

Claims

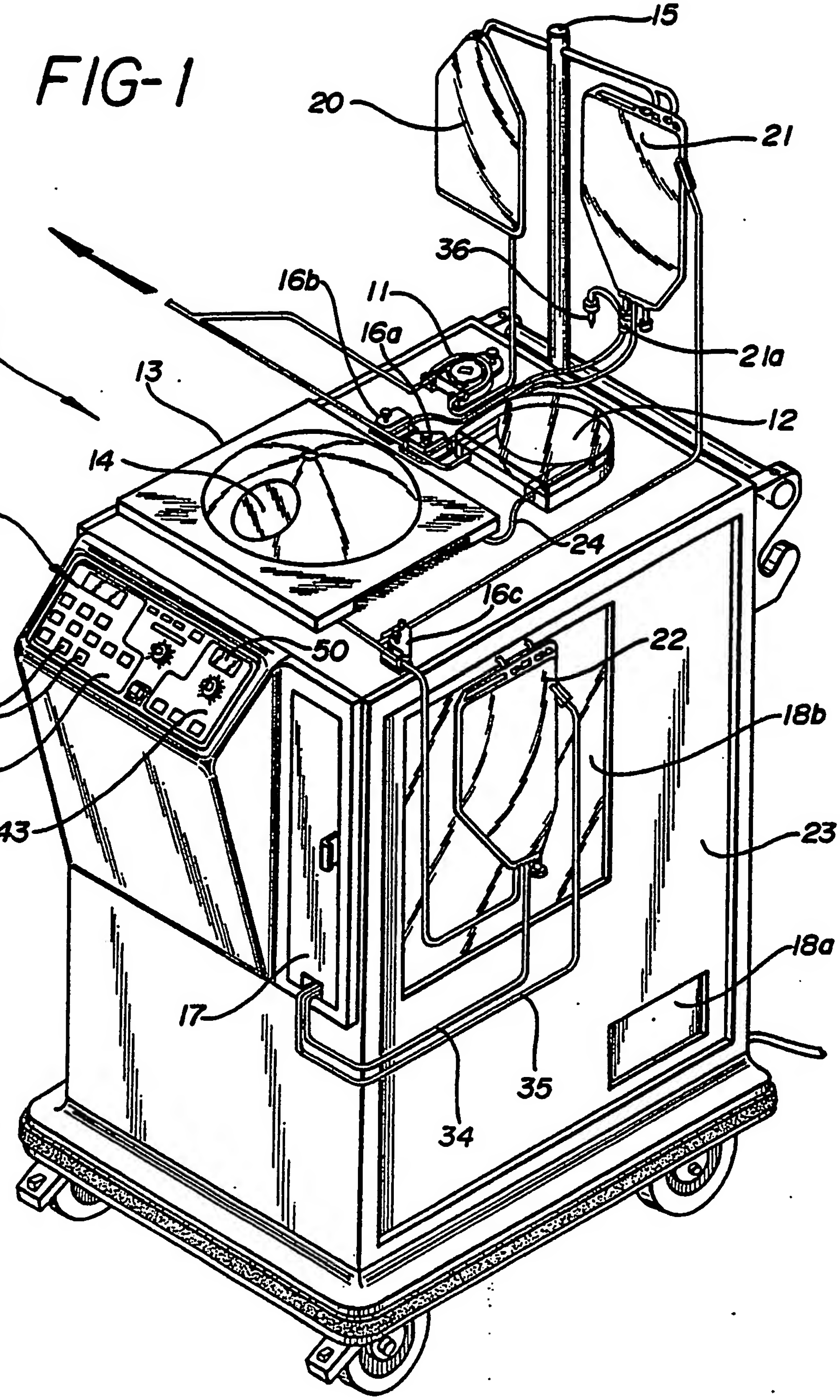
1. In a patient treatment system wherein patient fluids, in contact with a photoactivatable agent, are irradiated extracorporeally in an irradiation chamber for photoactivating the photoactivatable agent, and returning said treated cells to the patient, a combination comprising a peristaltic roller pump having three or more rollers, a pump block associated with said irradiation chamber having hollow tubing in fluid communication with said irradiation chamber, said pump block further comprising an arcuate track having an angle ϕ satisfying the following formula:
$180 \geq \phi \geq 360/n$ where n is the number of rollers associated with said peristaltic roller pump, said hollow tubing following the contour of said arcuate track, said pump block adapted to slidably engage said peristaltic roller pump whereby upon engagement, said hollow tubing is occluded by at least one roller.

2. The combination as provided in Claim 1 wherein said peristaltic roller pump comprises a pump with three rollers, said rollers mounted on arms, one end of which are pivotably mounted on said peristaltic roller pump, and the other end of said arms being urged outward from the center of said peristaltic pump by resilient means associated with said pump.

3. The combination as set forth in Claim 2 further comprising travel limiting means associated with the end of said pump having said resilient means for limiting the outward movement of said arm and said roller.

4. The combination of any one of claims 1 to 3 wherein said peristaltic roller pump further comprises alignment means for facilitating engagement of said rollers of said peristaltic roller pump with said arcuate track of said pump block upon sliding engagement therebetween.

FIG-1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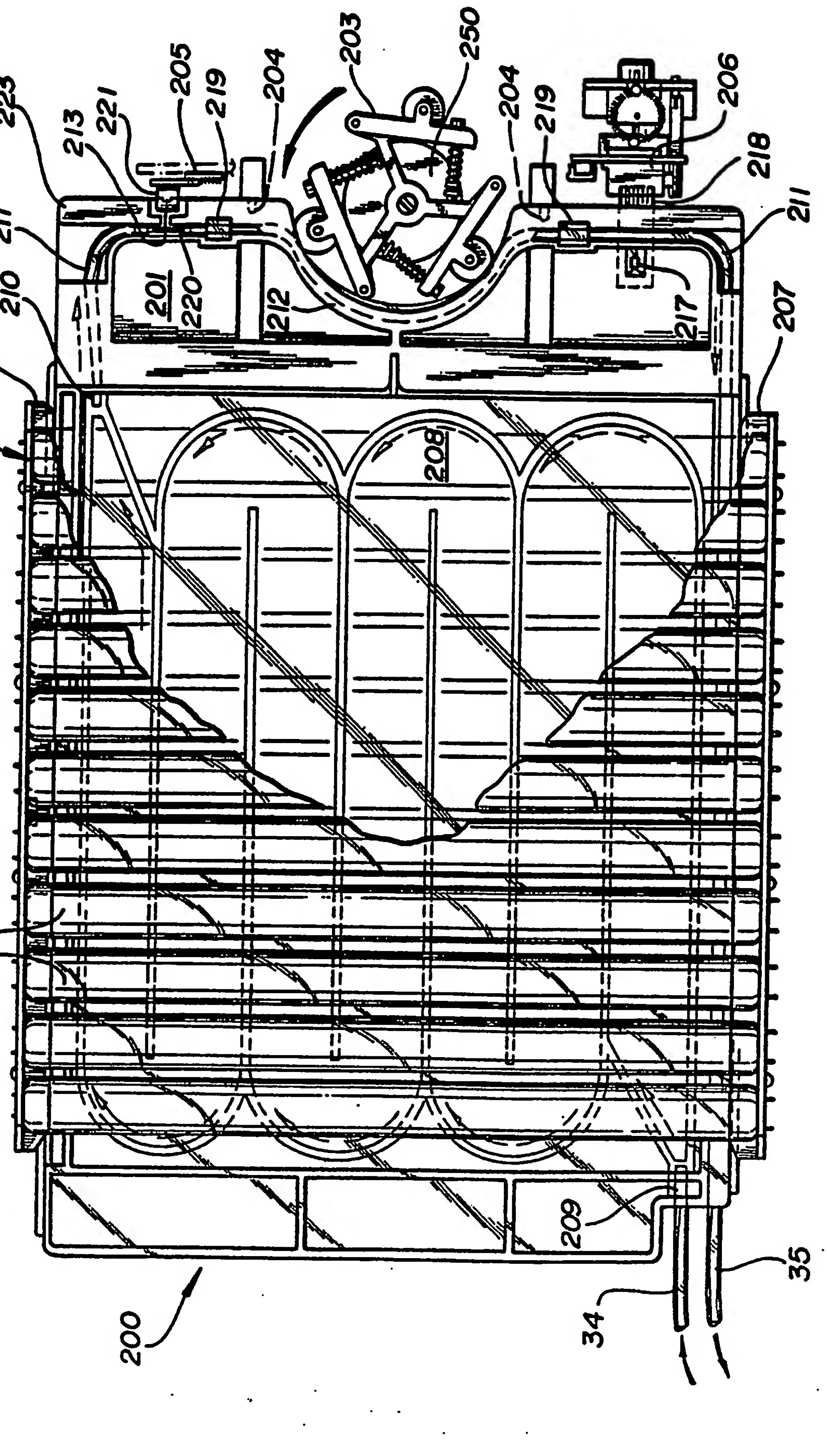
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FIG-2

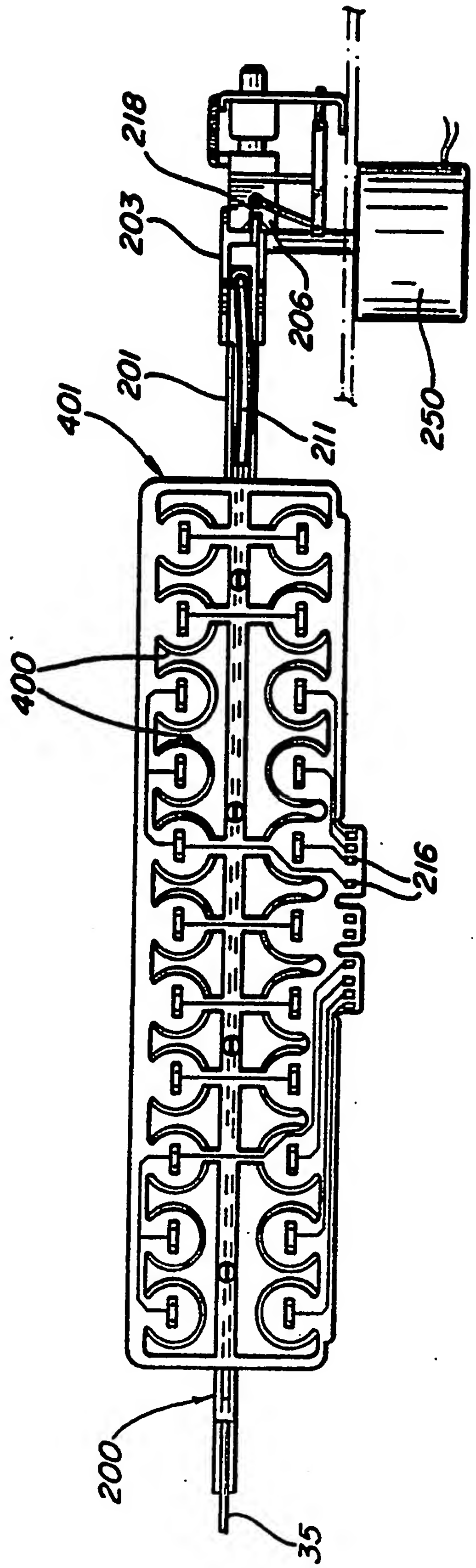

FIG-3

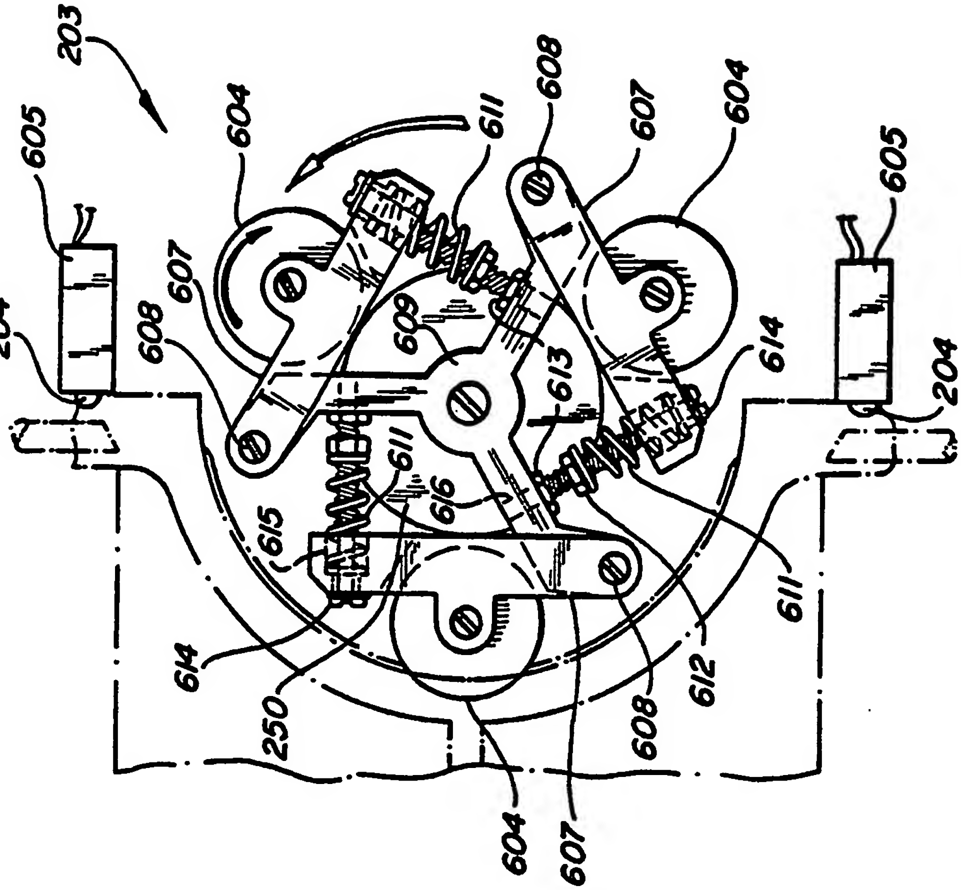
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FIG-6

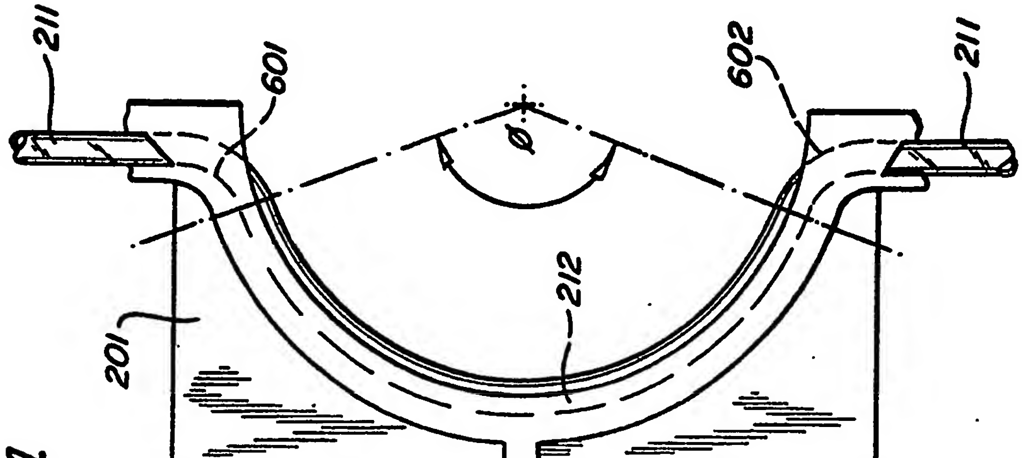
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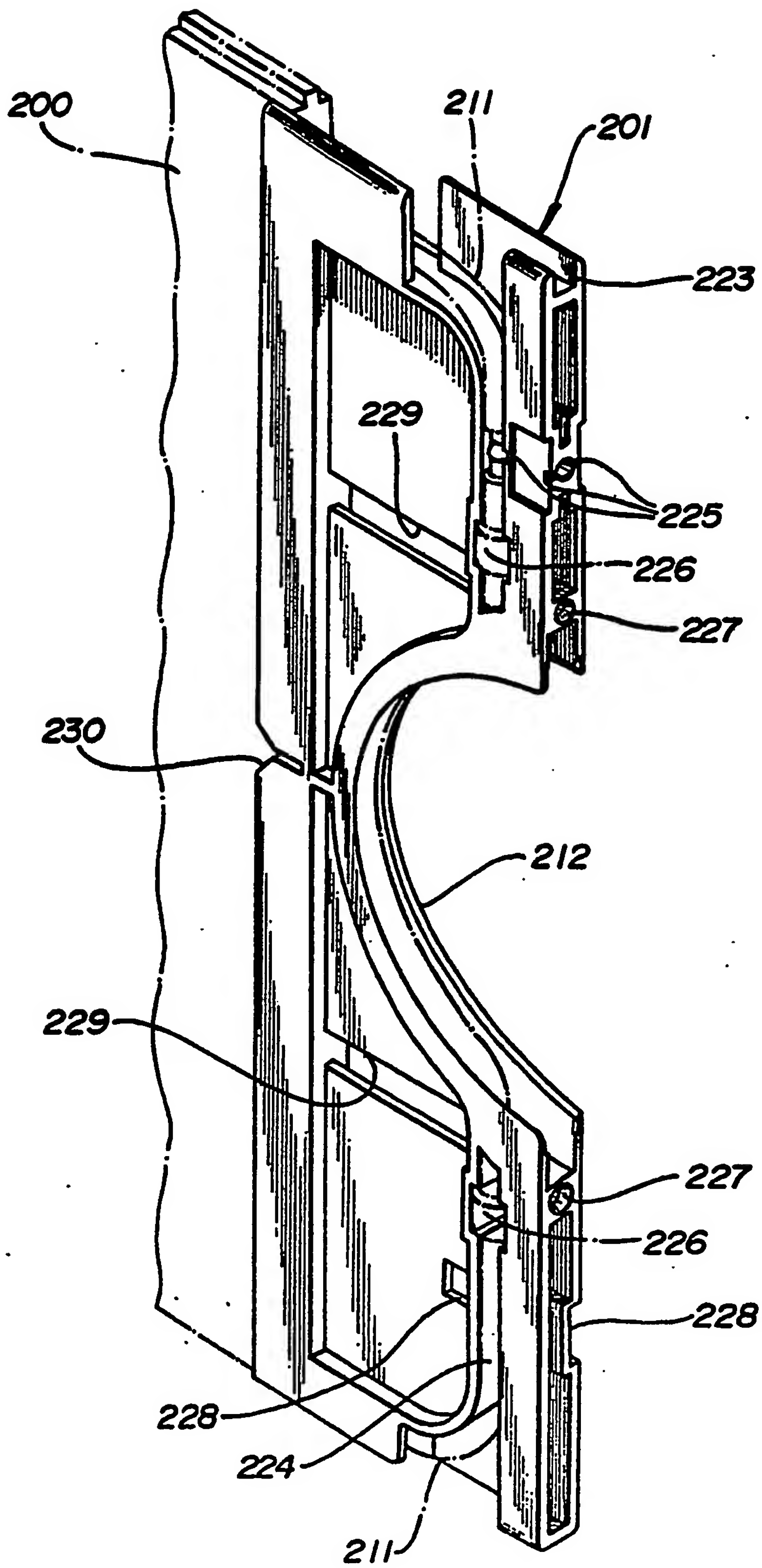
FIG-4

FIG-5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European Patent Office

EUROPEAN SEARCH REPORT

Application number

EP 87 30 1723

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
D,A	US-A-4 398 906 (EDELSON) * claim 1; column 7, lines 40-50; figure 1 * ---	1	A 61 M 1/10 A 61 M 1/36
A	FR-A-2 338 709 (BAXTER TRAVENOL LABORATORIES) * claim 12; page 11, lines 30-39; figures 11, 14 * ---	1,3,4	
A	DE-A-2 204 800 (KLUSCH) * claim 1; page 2, lines 11-18; figure 3 * ---	1	
A	DE-A-1 807 979 (GAMBRO AG) * claim 1,; page 3, lines 11-20; page 4, lines 1-6, figure 1 * -----	2,4	**TECHNICAL FIELDS SEARCHED (Int. Cl.4)** A 61 M 1/00 A 61 M 5/00 F 04 B 49/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	08-07-1987	PAPA E.R.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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& : member of the same patent family, corresponding document

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